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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,607	06/26/2003	Elizabeth Jane Lawlor	GM10253V-3	6375

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,607	LAWLOR, ELIZABETH JANE	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08844059.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/04 + 6/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 14 and 21-26 are pending in the case.

Receipt of Information Disclosure Statements on 6/26/03 and 5/13/04, and response to the restriction requirement and amendments to the claims on 10/12/04, are hereby acknowledged.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the claim for priority filed 6/23/03, applicants state that they claim priority to Application No. 10/187,641, which is a continuation of 10/025,189, which is a continuation of 09/432,695, which is a divisional of 08/844,059. However, applications 10/187,641 and 10/025,189 do not contain adequate support for the claims of the instant application, since there is no disclosure in either application of antagonists of the protein whose sequence is shown in SEQ ID NO:2 of the instant application. Therefore,

priority to the parent applications is denied, and the priority accorded this application is the instant filing date, 6/26/03.

In addition, applications 10/187,641 and 10/025,189 differ significantly in their content from the instant specification, and therefore, the instant application is not properly a continuation of 10/187,641, and 10/187,641 is not properly a continuation of 10/025,189. Therefore, applicant's claim to priority has not been perfected. See MPEP 201.11.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims any antagonist which inhibits the activity or expression of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, or wherein the polypeptide further comprises a heterologous amino acid sequence fused to SEQ ID NO:2 (claims 14, 21 and 22); or any antagonist which inhibits the activity or expression

of a polypeptide wherein said polypeptide comprises a fragment of amino acid sequence set forth in SEQ ID NO:2 comprising at least 50, or at least 30, consecutive amino acids thereof, and wherein the fragment exhibits methionyl tRNA synthetase activity, or wherein the polypeptide further comprises a heterologous amino acid sequence fused to said fragment (claims 23-26). The claims read on a broad genus of antagonists with a particular function, ie. the ability to inhibit activity or expression of a polypeptide with a particular structure.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by function characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims any product which is an antagonist of the polypeptide which is the methionyl tRNA synthetase of Streptococcus pneumoniae whose sequence is disclosed in SEQ ID NO:2, or fusions or fragments thereof, without disclosing any structural information regarding these products. The specification only provides general teachings regarding methods of screening for possible antagonists at pages 26-27, and a general statement that "[p]otential antagonists include small organic molecules,

peptides, polypeptides and antibodies that bind to a polynucleotide or polypeptide of the invention and thereby inhibit or extinguish its activity. Potential antagonists also may be small organic molecules, a peptide, a polypeptide such as a closely related protein or antibody that binds the same sites on a binding molecules, such as a binding molecule, without inducing metS-induced activities, thereby preventing the action of metS by excluding metS from binding" and further, "[o]ther potential antagonists include antisense molecules" (page 27, lines 10-15). The specification provides no structural or specific functional characteristics of antagonists, nor is there any indication that the inventors actually implemented a method of isolating antagonists so as identify such a molecule. Because the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification, the instant specification has not satisfied the written description for the claimed genus. The recitation in the claims and specification of antagonists which are waiting to be discovered, does not satisfy the written description requirement.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one of skill in the art to envision a representative number of antagonists having the recited activity. Thus, the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Claim 14 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in the present rejection;

The nature of the invention: The instant claims are drawn to antagonists which inhibit the activity or expression of a polypeptide comprising an amino acid sequence of SEQ ID NO:2, or fragments or fusions to heterologous proteins, of SEQ ID NO:2. The specification teaches that the antagonists may be used to inhibit and treat various diseases caused by the pathogenic bacteria *S. pneumoniae* (page 28 of the specification). Thus the nature of the invention is products which are intended to be used in vivo in order to treat infection by a bacterial agent. The claims encompass products that are not described in the specification, and indeed may not have been identified anywhere. Thus the invention encompasses "reach-through" claims that attempt to gain patent coverage for subject matter that cannot be made in view of the instant specification alone. It is noted specifically that the ability to "identify" is not equivalent to the ability to "make and use", which is the standard for meeting the enablement requirement.

Scope of the art: The scope of the invention is very broad, encompassing any molecule having the ability to inhibit expression or activity of a particular polypeptide.

This includes molecules that have not been identified or described in the specification (or anywhere).

The state of the prior art, and the predictability or unpredictability of the art: The claims as drafted comprise any molecule which can act to inhibit expression or activity of a particular polypeptide, ie. the methionyl tRNA synthetase of *S. pneumoniae.* There is much unpredictability in the field of designing agents which will specifically inhibit the expression or activity of a polypeptide, especially when the inhibition may include in vivo conditions. For instance, regarding the use of antisense molecules as inhibitors (which is the one molecule possibly encompassed by the claims whose general structural nature, although not particular structure, can be envisioned, i.e. it is a nucleic acid), Branch (TIBS Vol. 23, pp.45-50, 1998) teaches, e.g. as summarized in the Abstract, that there was no clear demonstration of an antisense molecule acting as an antisense against the intended single target gene as of that date. Clearly, use of antisense agents was far from routine. Branch also shows that mere knowledge of a potential target gene does not predict that an antisense would actually function as planned, and that its design was far from routine in the art. Therefore, the one agent (i.e. antisense molecules) whose structure could perhaps be designed knowing the structure of the gene encoding the polypeptide of SEQ ID NO:2, was not able to be routinely made by one of ordinary skill in the art.

The amount of direction or guidance presented in the specification, and the presence or absence of working examples:

The specification have presented no direction or guidance in the specification for the isolation of antagonists of the recited polypeptides, other than general statements such as found on page 26, i.e. "[t]he method of screening may involve high-throughput techniques". There are no working examples of methods of isolation of antagonists. Furthermore, there is no working examples concerning how to use the claimed products. There is no teaching regarding how to administer the claimed antagonists so as to effect treatment of infections caused by *S. pneumoniae.*

In summary, the claims fail to meet the enablement requirement for the "how to make" and the "how to use" prong of 35 USC 112p.1, since (1) the instant fact pattern fails to disclose any particular structure for the claimed antagonist; the specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to have prepared the claimed antagonist without undue experimentation, and (2) the specification does not teach how to administer the claimed antagonists compounds so as to effect a viable treatment for bacterial infection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, and by dependence, claim 22, are vague and indefinite, since claim 21 is dependent on cancelled claim 11. Therefore, the intended metes and bounds of the intended subject matter cannot be determined. In the interest of compact prosecution, the claims have been examined as if they were dependent on claim 14.

Claim 22 is vague and indefinite since it recites that "the polypeptide consists of SEQ ID NO:2, and yet it is dependent on claim 21, which recites that "the polypeptide further comprises a heterologous amino acid sequence fused to SEQ ID NO:2". Therefore, it cannot be determined what is intended by the claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Berge et al. (US Patent 6,320,051) in view of Dorland's Illustrated Medical Dictionary (27th Ed., W.B. Saunders Co., Harcourt Brace Jovanovich, Inc., 1988).

Berge et al. disclose molecules which are antagonists which inhibit the activity of the polypeptide which is the methionyl tRNA synthetase, including that of Streptococcus pneumoniae (see abstract, see column 8 line 66 – column 9, line 5). The instant specification discloses that the polypeptide whose amino acid sequence is set forth in SEQ ID NO:2 is that of the methionyl tRNA synthetase of S. pneumoniae (page 8-14). It is noted that as defined in Dorland's Illustrated Medical Dictionary, an "antagonist" is "a substance that tends to nullify the action of another". Therefore, the molecules

disclosed by Berge et al., which are disclosed to act against S. pneumoniae by inhibiting the activity of methionyl tRNA synthetase, meet the limitations of the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. Vogel, Ph.D.
Patent Examiner